

Introduction

Up to **24% of the general population** is diagnosticated of **chronic constipation** ^[1], leading to negative **clinical and social consequences** for patients, and **additional costs** for the health care systems ^[2].

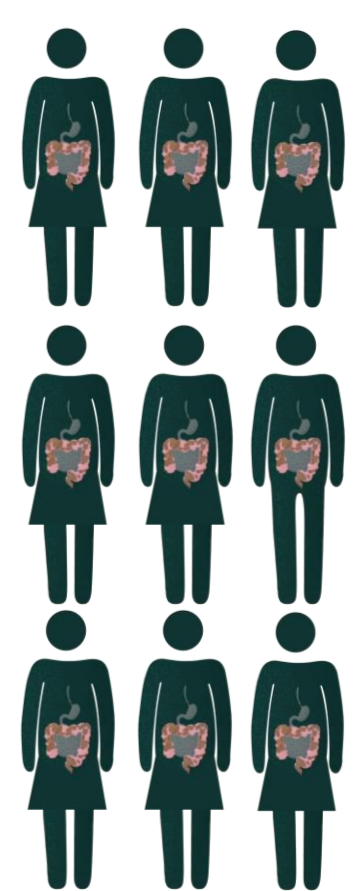
Intermittent colonic exoperistalsis (ICE) treatment administered with a medical device, is a **non-invasive, non-pharmacological solution** for the treatment of **chronic constipation** of distinct etiology. **The ICE medical device has been proven** in a multicentric clinical trial to be **safe and effective** in constipation from either NBD or idiopathic etiology ^[3].

Here, the objective was **to assess the efficacy, tolerability, and satisfaction with the ICE device in people with chronic functional constipation, based on real-world data.**

References

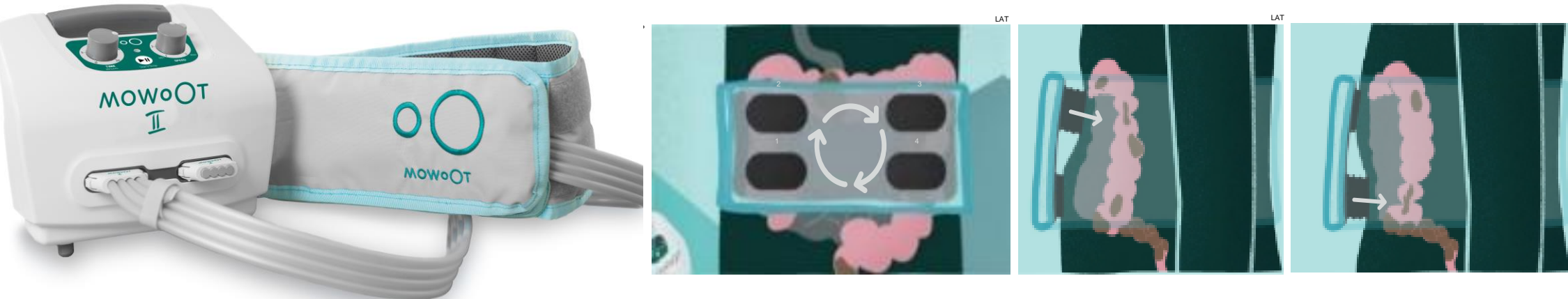
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Subjects and Methods



- **Adult** patients with **chronic functional constipation** according to Rome criteria ^[4, 5]
- **with or without** previous diagnosis of **slow bowel transit**
- recruited in 4 hospitals in **Germany** ^[6]

Treatment consisted in **15-30 min/day ICE at home**



The ICE device is composed of an exoperistaltic belt connected to a pneumatic desktop device, which contains the source of energy and the panel control. The active elements of the belt inflate and deflate sequentially on the ascendant and descendent colon, emulating natural peristaltic contractions and colon massage techniques, thus administering the intermittent colonic exoperistaltis treatment.

In-use-evaluation was performed through anonymous, **structured feedbacks** collected at **baseline (Feedback F1)** and after some time **under ICE treatment (Feedback F2)**.

Efficacy variables and use of laxatives were included in the structured questionnaires. Satisfaction, Tolerability, and Usability were valued by patients from 1 (very high) to 6 (very low).

Contact

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Results

Table 1.

Sample description	ALL	Slow Transit
N	18	12
Treatment duration (months)	6,33 (5,18) min 0,5; max 16	6,29 (5,12) min 0,9; max 16
Age (yr)	49,06 (18,52) min 18; max 75	41,92 (17,83) min 18; max 55
Male	1	0
Female	17	12

No one reported **any serious adverse event**. **Six patients (33%)** described **occasional low to moderate abdominal pain**, which **did not affect** the treatment **compliance**.

There was a significant **reduction by ~1h in time spent per evacuation** and an **overall improvement in bowel function** (Table 2). **Six patients stopped** and **3 reduced oral laxatives** (Table 3). **Satisfaction with the ICE treatment** was rated as **high or very high** among most of patients (Table 4).

Table 2. Results shown as mean(SD); Paired t-test or Wilcoxon.

Efficacy		PRE (F1)	TREAT (F2)	F2-F1	P
# Bowel mov /week	slowT	2,67 (1,91)	5,32 (3,23)	2,65	0,0037
	ALL	2,61 (1,81)	5,62 (2,93)	3,01	<0,0001
Time/evacuation (min)	slowT	148,3(164,7)	72,1 (79,5)	-76,00	0,0447
	ALL	105,9(146,4)	50,9 (71,1)	-55,00	0,0308
Average Bristol (1-7)	slowT	2,00 (1,13)	3,75 (1,91)	1,75	0,0084
	ALL	2,84 (1,81)	3,94 (1,85)	1,10	0,0099
Satisfact. Bow. funct&manag (1-6)	slowT	5,75 (0,45)	3,42 (2,23)	-2,33	0,0206
	ALL	5,50 (0,98)	3,06 (2,01)	-2,44	0,0034

Table 3. Results are shown as number (n) of patients.

Use of laxatives		Baseline (F1)	Treat (F2)	P Chi ²
Slow Transit	Yes or Same	11	4	0,0094
	No or Less	1	8	
ALL	Yes or Same	16	7	0,0018
	No or Less	2	11	

Conclusions

This structured feedback in the out-patient sector with **real-world data** demonstrates the medical **benefit of Intermittent Colonic Exoperistalsis in functional constipated patients** with or without slow bowel transit.

The **high number of satisfied patients** relates with the clinically significant **amelioration in their bowel function and quality of life**.

Due to the improvement in the patient's health and quality of life, and to the ease of use, the **patients can easily use the ICE device in homecare-settings**.

Therefore, **the ICE device has the potential to substitute more conservative approaches in bowel management strategies of the general population**.

Table 4. Results are shown as number and percentage of patients.

Satisfaction w/ICE treat at F2 [n(%)]		very high & high (1-2)	Normal (3-4)	low & very Low (5-6)
Overall efficacy	slowT	9 (75,0%)	3 (25,0%)	0 (0%)
	ALL	13 (76,5%)	4 (23,5%)	0 (0%)
Tolerability	slowT	9 (81,8%)	2 (18,2%)	0 (0%)
	ALL	14 (87,5%)	2 (12,5%)	0 (0%)
Usability	slowT	12 (100%)	0 (0%)	0 (0%)
	ALL	15 (88,2%)	2 (11,8%)	0 (0%)